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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,937	10/07/2003	Thomas B. Stanford JR.	B-4588NP 620930-1	6021
<div>7590 Richard P. Berg, Esq. c/o LADAS &amp; PARRY Suite 2100 5670 Wilshire Boulevard Los Angeles, CA 90036-5679</div>			<div>EXAMINER MARTIN, PAUL C</div>	
			<div>ART UNIT 1657</div>	<div>PAPER NUMBER</div>
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/09/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/680,937	STANFORD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul C. Martin	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 14-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/26/04, 4/15/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Claims 14-32 are pending in this application.

### ***Election/Restrictions***

Applicant's election with traverse of Group II (Claims 14-30 and including new claims 31 and 32) and species: (expressed enzyme:  $\alpha$ -amylase) and (product: gluconic acid) in the reply filed on 04/27/06 and election with traverse of the species: (element: polyaniline), (enzyme: glucose oxidase), (substrate: glass), and (organosilane: tetramethoxy orthosilicate) in the reply filed on 12/20/06 is acknowledged. The traversal is on the ground(s) that a search of all of the species would not pose a serious search burden. This is not found persuasive because all of the claims and species contained therein are independent and distinct from one another such that a search for embodiment composed of one set of species would not be co-extensive with an embodiment composed of another set of species. For example, to conduct a literature search for invention in Group II that is constituted of different enzymes, one would be searching for a total number of combinations that will be a factorial of at least 20 with each one of the ingredients up to ingredient number 1 (i.e.  $20 \times 19$ ,  $10 \times 18$ ,  $20 \times 17$ ,  $20 \times 16$  and up to.... $20 \times 1$ ). Thus, this group alone will exert an enormous search burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

The use of the trademark Lab-on-a-Chip has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites the limitation "the enzyme" and "said enzyme" in lines 4 and 6. There is insufficient antecedent basis for this limitation in the claim. More specifically, the claim does not clearly delineate whether one or more enzymes is involved in the method or specifically identify said enzyme(s). It is suggested that the claims recite something like a first or sol-gel-enzyme and a second or organism-enzyme.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keyes (US 4,169,765) in view of Yamagishi *et al.* (US 6,730,212 B1).

Keyes teaches method for the detection of  $\alpha$ -amylase produced by an organism, using a sensor comprising a substrate-surface immobilized amylose starch reagent is contacted with a sample containing  $\alpha$ -amylase expressed by an organism, the  $\alpha$ -amylase catalyzes the reaction of starch to form oligosaccharides which react with immobilized glucoamylase to form glucose, glucose oxidation is catalyzed by immobilized glucose oxidase to form gluconic acid and  $H_2O_2$ , wherein the amount glucose is measured by detecting the amount of current generated by the  $H_2O_2$  with an electrode (Column 4, Lines 1-20 and Column 30, Claims 1-3).

Keyes teaches that the reagents can be immobilized by any of the known methods for immobilization glucose oxidase can be immobilized by covalent coupling to an amino-functional silane, or immobilized in polyacrylic polymers or polyacrylamide gels (Column 6, Lines 36-58).

Keyes does not teach a method wherein a sol gel matrix covers a glass substrate and the electrodes, wherein the electrodes are interdigitated and comprise polyaniline, and the sol-gel comprises tetramethoxy orthosilicate and encapsulates the glucose oxidase, reactant and transducer material, wherein the generated  $H_2O_2$  modulates the electrical resistance of an inherently conductive, water-soluble polyaniline polymer transducer.

Yamagishi *et al.* teaches a sensor comprising a glass substrate on which interdigitated, polyaniline comprising electrodes are deposited, covered by a sol-gel matrix containing the inherently conductive, water-soluble polyaniline polymer tetramethoxy orthosilicate (TMOS) and encapsulating an enzyme (glucose oxidase), wherein glucose oxidation is catalyzed by the glucose oxidase to form gluconic acid and  $H_2O_2$  modulating the electrical resistance of the conductive polymer detected by applying voltage and registering the change in current with an amperometer (Column 3, Lines 30-61 and Columns 15 and 16, Claims 1-3 and Column 17, Claims 9-12 and 14).

Yamagishi *et al.* teaches that prior sensor methods including surface acoustic wave, mass spectroscopy, infrared spectroscopy and gas chromatography are directed toward laboratory analysis rather than field application and have the disadvantages of having large size, long analysis times, complicated electronics support, lack of specificity and high cost (Column 2, Lines 57-67) while the enzyme-encapsulated, conductive polymer sol-gel biosensor has the advantages of being simple, inexpensive, accurate and adaptable to field detection of biological pathogens or chemical agents without the need for “wet” chemistry (Column 3, Lines 1-13).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the enzyme immobilized sensor method for the detection of  $\alpha$ -amylase produced by an organism as taught by Keyes above with the enzyme-encapsulated, conductive polymer sol-gel biosensor as taught by Yamagishi *et al.* above because both methods are drawn to the use of immobilized enzymatic biosensors in the detection and measurement of an environmental enzyme of interest. One of ordinary skill in the art would have been motivated to make this combination because of the advantages described by Yamagishi *et al.* above, such as being simple, inexpensive, accurate and adaptable to field detection of biological pathogens or chemical agents without the need for “wet” chemistry. One of skill in the art would have

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recognized that the use of an ohmmeter to measure the electrical resistance instead of the ammeter used to measure current as taught by Yamagishi *et al.* would have been a matter of preference as both methods are used to determine electrical current. In particular, the method of Yamagishi *et al.* is advantageous over the solitary method of Keyes, which relies on laboratory specific analytical techniques such as polarography, mass spectroscopy and "wet" chemistry. There would have been a reasonable expectation of success in making this combination because both methods rely upon substrate immobilized enzyme technology, particularly the use of glucose oxidase in the oxidation of glucose to form gluconic acid and hydrogen peroxide and the measurement of the electrical current derived from this reaction.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3/27/07

Paul Martin  
Examiner  
Art Unit 1657

A handwritten signature in black ink, appearing to read "Jon Weber", with a large, stylized initial "J" and a cursive "W".

**Jon Weber**  
**Supervisory Patent Examiner**